NOV - 5 2003

K032405

510(K) SUMMARY
June 30, 2003

8.0 Summary of Safety and Effectiveness

8.1	Submitter's Name and Address:	Biogen 14 Cambridge Center Cambridge, MA 02142
	Contact Person:	Michael Poirier Tel: 1-617-679-6459 Fax: 1-617-679-3170
8.2	Trade/Proprietary Name:	Invisiject™ Reusable Auto-Injector
8.3	Common/Usual Name:	Auto-injector
8.4	Classification Name:	Introducer, Syringe Needle

8.5 Substantial Equivalence:

The Invisiject™ Reusable Auto-Injector is substantially equivalent to the B-D Auto-Injector (K974678), the Owen Mumford Autoject 2 (K013362), the standard Piston Syringe (Numerous Devices) and Meridian's EpiPen® (NDA -19-430). The attached documentation supports the equivalence.

8.6 Description:

The Invisiject™ Reusable Auto-Injector is a reusable, spring-loaded injection device that is designed to deliver 0.5 mL of AVONEX® from a pre-filled syringe. Using the Auto-Injector instead of direct injection with the pre-filled syringe provides an alternative method of injection to address needle phobia and injection anxiety by covering the syringe and needle during the injection process. The product consists of four separate components that are used to prepare and inject the drug from the pre-filled syringe through the single lumen hypodermic needle. The components, a Syringe Adapter, Syringe Holder, Base Unit, and Power Pack are packaged together in a plastic case, which doubles as the Handling Console used for assembly and charging the Power Pack. The AVONEX® pre-filled syringes and commercially available single lumen hypodermic needles are provided separately.

8.7 Intended Use:

The Invisiject™ Reusable Auto-Injector is a reusable device intended to be used by the patient to assist with the self-administered injection of a fixed dose of AVONEX® from a pre-filled syringe through a single lumen hypodermic needle. The auto-injectors are intended to be used in any setting including the home.

8.8 Technological Characteristics:

The technological characteristics of the AVONEX® Reusable Auto-Injector are the same as products currently legally marketed in the USA

8.9 Performance Data:

Performance of the Invisiject™ Reusable Auto-Injector was assessed using applicable sections and methods specified in the ISO standard, ISO 11608-1, "Pen-injectors for Medical Use - Part 1: Requirements and Test Methods". Penetration depth, activation force for injection, loading force and Injection time were also assessed. The device met all requirements and specifications.

8.10 Conclusion:

Biogen concludes based on the information presented that the Invisiject™ Reusable Auto-Injector is substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Biogen
Mr. Michael Poirier
Associate Director Regulatory Affairs
14 Cambridge Center
Cambridge, Massachusetts 02142

Re: K032425
Trade/Device Name: Invisiject ™ Reusable Auto-Injector
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: August 5, 2003
Received: August 7, 2003

Dear Mr. Poirier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

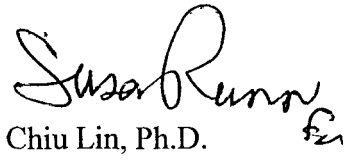
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number: K032425

Device Name: Invisiject™ Reusable Auto-Injector

Indications For Use: The Invisiject™ Reusable Auto-Injector is a reusable device indicated for use by the patient to assist with the self-administered injection of a fixed dose of AVONEX® from a pre-filled syringe through a single lumen hypodermic needle. The auto-injectors are intended to be used in any setting including the home.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucenta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032425

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.19)